The National Congenital Heart Disease Audit

Procedures for CONGENITAL HEART DISEASE

Data Quality Audit For the year 2020/21

Barts Health NHS Trust

Wednesday 4 August 2021

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Summary

Prior to the theatre and cath lab log book validation at this visit, the data submission to NCHDA from the cardiac department of the Adult Congenital Heart Disease unit Barts Health NHS Trust indicated that a total of 284 procedures (44 surgical, 221 catheter procedures, 19 others, 2 deaths) were undertaken during the data collection year April 2020 to March 2021. This represents approximately 35% fewer procedures during a time of the SARS-COV-2 pandemic.

This validation visit has been fully funded by the Barts Health NHS Trust. This visit was supported remotely by the NCHDA clinical audit nurse via a MS Teams facility and on site in person by Dr Andrew Tometzki, Consultant in Congenital Cardiology.

In April 2015 The Heart Hospital cardiac unit moved to the St Bartholomews' NHS foundation Trust site (SBH).

There are 5 consultant cardiologists at SBH that specialise in adult congenital cardiology. There are 2 Congenital surgeons who visit to undertake Congenital cardiac operations at SBH who also practice at Great Ormond Street Hospital for Children which is in an adjacent NHS Foundation Trust.

At the new SBH unit, there is a 1.0 WTE Clinical Nurse Specialist (CNS) for NCHDA cardiac audit and a data manager who coordinate the collection and submission of these data. These individuals also have full responsibility for the National Adult Cardiac Surgery Audit (NACSA) registry.

At SBH there is a specially created web based Dendrite Intellect data collection system for NCHDA data. Data are collected in real time at the point of treatment.

Consent for External Validation of Notes.

Since May 2018, the General Data Protection Regulation has required that patients are made aware of how their data are collected and used. As such, NCHDA now no longer requires a specific consent to examine hospital case notes. If a patient has expressed a wish not to allow their case notes to be examined by others not connected to their care, these wishes will be respected.

A random list of case notes; 20 Samples and 10 Reserves were provided approximately 4 weeks prior to the Validation Visit. On the day 2 sets of case notes were made available from the Reserve list. These 20 patients had 25 procedures7 (5 operations and 20 catheter procedures)

Actions Undertaken Following Previous Validation Visit in 2020: None reported

Data Quality Indicator

The DQI for the Trust for this visit (previous years in parentheses) is calculated to be **97.5%** (98, 96.6, 96.5) with domain scores Demographics 1.0 (1.0, 1.0, 1.0), Pre Procedure .96 (.97, .925, .93), Procedure .96 (.95, .94,.94), and Outcome .98 (1.0, 1.0, .99).

This represents a very good score. Well done. There were 1018 variables reviewed for 20 patients who underwent 5 operations and 25 catheter procedures. 32 errors or discrepancies were identified.

The fields where most discrepancies are:

Pre Procedure Comorbidities 7
Pre Procedure Ventricular Function 5

Since 2009, separate DQI scores are being calculated for both catheters and surgery. The DQI is calculated from the case note review only. A minimum number of 5 records are required in either group for this to be done.

Year of visit	Data year being validated	Surgery Procedures	Catheter Procedures
2014(i)	**12/13**	**96.5%**	**93.5%**
2014(ii)	**13/14**	**89%**	**88.75%**
2015	**14/15**	**93.5%**	**95.25%**
2016	**15/16**	**91.75%**	**93.75%**
2017	**16/17**	**97.75%**	**96%**
2018	**17/18**	**100% (3 records only)**	**96.5%**
2019	**18/19**	**99%**	**95.75%**
2020	**19/20**	**99.25%**	**97.25%**
2021	**20/21**	**95.75%**	**97.75%**

The NCHDA pre visit Questionnaire confirmed that there are good processes and procedures in place with regard to:

Data Security and Management
Validation and Quality Assurance

Training in Data Management

Information Governance Training

There is or are identified accountable person/people for NCHDA data quality and information validity

Data Submissions are Timely and Accurate.

Introduction

Prior to the validation visit, the Congenital NCHDA return from the cardiac department at St Bartholomew's Hospital (SBH) indicate that a total of 284 procedures (44 surgical, 221 catheter procedures, 19 others, 2 deaths) were undertaken during the data collection year April 2020 to March 2021.

The accuracy of the NCHDA data return was checked against each set of notes. The accuracy was then recorded on a database to enable the Data Quality Indicator (DQI) to be scored.

Review of notes at Barts Health NHS Trust

On the day 18 sets of case notes from the Sample list supplied were available. 2 case notes were available from the Reserve list. The hospital notes packs for each patient were mostly printed from the ePR and prepared for the Validation Visit with all key documents indicated by temporary sticky notes to assist with finding information. SBH are 'paper-lite' with a mixture of electronic 'e' noting systems and with some retention of paper bound files.

1. The NHS Number was found in the hospital notes seen at this visit as the DBM had printed out a registration document which has a field for this identifier.
2. As noted previously, there does not appear to be consistent documentation of data items such as NYHA, diabetes, pulmonary or ischaemic heart disease in the hospital notes yet but it is improving. These fields are part of the NCHDA dataset.
3. As previously described, there does not appear to be consistent documentation of time of skin puncture to time of sheath removal in catheter procedures descriptions although it was reported at this visit this data point is recorded in Labyrinth.
4. For patients who have single ventricles it is only necessary to complete the field for systemic ventricular function.
5. Discharge destination (for example home/other specialty in same hospital/convalescence) did not always appear to be recorded in the patients daily narrative notes.
6. Make, model and serial/lot number of any device left in the patient is required to be submitted to NCHDA
7. Regular reverse validation of data submitted to NCHDA is promoted as good practice and is an excellent way to gauge quickly and easily if data are correct, accurate and complete.

Review of the Theatre log books

There are reported to be 10 cardiac operating theatres at SBH. The local NCHDA Data Manager offered the Reviewers extracts from the Cerner Millennium Surgery Scheduler (Surginet).

It was much easier to check case ascertainment across multiple theatres for known congenital cardiac surgeons in digital datasheets if all the relevant data points are collected. For instance Surginet does not record the patients diagnosis. It was difficult to scrutinise entries for younger patients whose procedures were not performed by known congenital surgeons as the diagnoses does not appear to be routinely recorded on each entry. Descriptions of operations were often stated as 'other operative procedure' which was not helpful.

- 3 surgical records were identified that may be suitable for inclusion in NCHDA
- 2 submitted records appear to have errors in them

Review of the Cath lab log books

There are reported to be 10 cardiac catheter labs at SBH. The local NCHDA Data Manager offered the Reviewers extracts from the Gallery Partnership Labyrinth Cardiac Catheter Scheduler. This is essentially a booking system and does not appear to support OPCS or ICD10 codes. It was extremely difficult sometimes to identify exactly what procedure had been performed on the date stated and whether or not it was for congenital heart disease. Some patients appeared to have multiple entries.

- 14 submitted catheter records may have errors in them, mainly related to incorrect Procedure Type selection
- 1 submitted record was not validated in the Labyrinth export
- 3 records were identified in Labyrinth that may be suitable for inclusion in NCHDA
- 2 records for the same patient appear to be for procedures for acquired disease and if so, these should be removed from the NCHDA database
- ILR (Loop) procedures have not been required for NCHDA submission since April 2019
- In the cath lab if it is the planned intention to use a device for closure of a defect but the packet of the device is not opened after measurement, this procedure should be submitted as a Diagnostic procedure not a Catheter Intervention.

Validation of Deceased Patients Diagnostic and Procedure Coding

Commencing with the validation of the 2013/14 data, the National Congenital Heart Disease Audit wish to verify the demographic, diagnostic and procedural data of deceased patients included in the year under review. The diagnosis and procedure coding will also be validated. 2 post procedural deaths were submitted in the data from SBH for the year 2020/2021.

1. 1 record may have an incomplete previous procedure listing
2. 1 record appears to have incomplete comorbidity fields
3. Both records appear to have incorrect Discharge Destinations
4. 1 patients record appears to have a support procedure (ECMO) absent in the submission

Case Note Audit 2020

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
1	Hospital Number	20	20		17	3
2	NHS Number	20	20		17	3
3	Surname	20	20		17	3
4	First Name	20	20		17	3
5	Sex	20	20		17	3
6	DOB	20	20		17	3
7	Ethnicity	20	20		17	3
8	Patient Status	20	20		17	3
9	Postcode	20	20		17	3
10	Pre Procedure Diagnosis	25	25		20	5
11	Previous Procedures	39	39		29	10
12	Patients Weight at Operation	24	25	1 incorrect	19/20	4/5
13	Height	23	25	2 incorrect	19/20	-
14	Ante Natal Diagnosis	-	-		-	5
15	Pre Proc Seizures	25	25		20	5
16	Pre Proc NYHA	25	25		20	5
17	Pre Proc Smoker	23	25	2 incorrect	19/20	5
18	Pre Proc Diabetes	25	25		20	5
19	Hx Pulmonary Dis	25	25		20	5
20	Pre Proc IHD	25	25		20	5
21	Comorbidity Present	25	25		20	5
22	Comorbid Conditions	19	26	7 absent	18/22	¼
23	Pre Proc Systemic Ventricular EF	22	25	3 incorrect	17/20	5
24	Pre Proc Sub Pul Ventricular EF	20	25	5 incorrect	15/20	5
25	Pre-proc valve/septal defect/ vessel size	8	8		8	0
26	Consultant	25	25		20	5

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
27	Date of Procedure + Time Start	25	25		20	5
28	Proc Urgency	25	25		20	5
29	Unplanned Proc	1	1		-	1
30	Single Operator	1	1		1	-
31	Operator 1	24	25	1 incorrect	20	4/5
32	Operator 1 Grade	25	25		20	5
33	Operator 2	22	24	2 incorrect	19	3/5
34	Operator 2 Grade	22	24	2 incorrect	19	3/5
35	Procedure Type	23	25	2 incorrect	20	5
36	Sternotomy Sequence	5	5		-	5
37	Operation Performed	25	25		20	5
38	Sizing balloon used for septal defect	10	10		10	-
39	No of stents or coils	1	1		1	-
40	Device Manufacturer	17	18	1 incorrect	13/14	4
41	Device Model	18	18		14	4
42	Device Ser No	17	18	1 incorrect	13/14	4
43	Device Size	11	11		7	4
44	Total Bypass Time	4	4		-	4
45	XClamp Time,	4	4		-	4
46	Total Arrest	4	4			-
47	Cath Proc Time,	19	20	1 absent	19/20	
48	Cath Fluro Time,	18	20	1 absent, 1 incorrect	18/20	
49	Cath Fluro Dose,	19	20	1 absent	19/20	

	Parameter	Total Score	Total No	Comments	Scores for Cardiology & Surgery	
					C	S
50	Duration of Post Op Intubation	5	5		-	5
51	Post Procedure Seizures	25	25		20	5
52	Post Proc Complications	6	6		2	4
53	Date of Discharge	25	25		20	5
54	Date of Death	2	2		1	1
55	Attribution of Death	2	2		1	1
56	Status at Discharge	25	25		20	5
57	Discharge Destination	23	25	2 incorrect	0/1	0/1

Data Quality Indicator Assessment:

The Overall Trust DQI = 97.5% Cardiology DQI = 97.75% Surgery DQI = 95.75%

DOMAIN	DOMAIN Score	
Demographics Hospital Number, NHS Number, Surname, First Name, DOB, Sex, Ethnicity, Postcode, Patient Status,	**Overall** 1.0	
	Card 1.0	**Surg** 1.0
Pre Procedure Pre procedure Diagnosis, Selected Previous Procedures, Patient Weight at Operation, Consultant, Antenatal Diagnosis, Pre Procedure Seizures, Comorbid Conditions, **Height, Pre Procedure NYHA, Pre Procedure Smoker, Pre Procedure Diabetes, Previous Pulmonary Disease, Pre Procedure Ischaemic Heart Disease, Comorbidity Present, Pre Procedure Systemic Ventricular Ejection Fraction, Pre Procedure Sub Pulmonary Ejection Fraction, Pre Procedure valve/septal defect/vessel size,** Note, the scores for his domain are affected by the selected previous procedure and pre procedure diagnosis	**Overall .96**	
	Card .96	**Surg** .94
Procedure Date of procedure, Operator 1, Operator 2 Cardiopulmonary Bypass used, Operator 1 grade, Operator 2 grade, Operation performed, Sternotomy sequence, Bypass Time, CircArrest, XClamp Time, Cath Proc Time, Cath Fluro Time, Cath Fluro Dose, **Time Start, Procedure Urgency, Unplanned Procedure, Single Operator, Sizing Balloon Used, No of Stents/Coils, Device Mfr, Device Model, Device Ser No, Device Size,**	**Overall** .96	
	Card .97	**Surg** .93
Outcome Duration of Post Op Intubation, Post Procedure Seizures, Date of Discharge, Date of Death, Status at Discharge, Discharge Destination. **Post Procedure Complications.**	**Overall** .98	
	Card .98	**Surg** .96

The Trust DQI = 97.5%

This DQI is based upon the domain scoring below. The methodology for this DQI is provided in the paper The NCHDA Audit – An Introduction to the Process.

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DOMAINS	2018	2019	2020	2021
Demographics	1.0	1.0	1.0	1.0
Pre Procedure	.93	.925	.97	.96
Procedure	.94	.94	.95	.96
Outcome	.99	1.0	1.0	.98

Conclusions

On the whole the NCHDA data were accurate, well documented and of good quality. The NCHDA Data Manager and analyst are to be commended for the considerable time spent in preparing many documents for this validation in a pandemic situation where they had to pivot from daily face to face working to working remotely.

The overall DQI has been maintained at a very good standard and increased to 98% since the last NCHDA Validation. There were 32 discrepancies in 1018 variables.

The Validation Team are aware that there is no regular reverse validation (where the submitted data retrieved and reviewed) of the data submitted to the NCHDA and the case notes are not always used to collect and/or validate data prior to submission. However, as stated in 2017 - 2019, there was an audit and quality process being devised as documented elsewhere to address this in particular and clinicians would be encouraged to take ownership of their data. It is not known at this visit what the current status of this process is.

As previously reported, there does not appear to be consistent documentation yet of data items such as NYHA, diabetes, pulmonary or ischaemic heart disease in the hospital notes that are part of the NCHDA dataset. This is improving gradually. It was very difficult again to find echo reports in some patients hospital notes and patients who have undergone electrophysiological procedures didn't always appear to have a discharge summary in the their hospital notes.

Discharge dates and destination do not always appear to be recorded in the patients daily narrative notes and there does not appear to be consistent documentation of time of skin puncture to time of sheath removal in catheter procedures. As previously reported, xray dose and length of time of xray exposure are currently required fields for NCHDA and it was again challenging to find this information in the hospital records of patients who had undergone pacing or electrophysiological procedures, although much of this data is reported to be recorded in Labyrinth. Surginet is an excellent operating room digital record but clearer more succinct descriptions of the procedures actually performed should be used rather than the non specific 'other operative procedure'.

Validation of Deceased Patients Demographic, Diagnostic and Procedure Coding

A very small number of discrepancies in the coding were identified but all other data appeared to be correct.

Recommendations

1. It is recommended that Standard Operating Protocols when finalised, are regularly reviewed for the Congenital data collection, to include detailed guidance on and **exactly who** is responsible (and in what timeframe) for;
    a. Ensuring that in line with the GDPR, all patients/parents and guardians are given full information of how their data are securely recorded, stored and where or who this information is shared with. And op out explained to patients/carers.
    b. Input of the NCHDA ACHD demographic, pre procedure, procedure and outcome data
    c. Input of the data for each patients procedure and at which point of the service delivery and in particular clear succinct description of the exact procedure performed in the digital log books used.
    d. Recording of implanted device data and the placement of product labels in an agreed portion of the patients hospital record that can easily be validated.
    e. Validity checking and completeness and the time intervals for feedback to responsible clinicians on this with a clear time scale and line of responsibility for rectifying any omissions or errors in both surgery and cardiology disciplines
    f. Leading the local review with the Lead Clinician for Congenital Heart Disease (and how frequently and in which forum for both disciplines)
    g. Making timely submissions where possible (monthly is recommended) and
    h. Timely reverse validation together with the Clinical Lead for Congenital Cardiology and the responsible clinicians
    i. Reviewing/Updating the SOP at timely intervals

3. It is recommended that the Congenital dataset fields should be set to mandatory in any of the data collection software used.
4. Documentation (either hard copy or on screen help) should be available to all staff in all areas where data are recorded real time.